

REMARKS

Claims 1-17 and 27 are pending in the present application. Applicants have carefully considered the Office Action mailed on July 22, 2008 and respond to the specific issues raised therein as follows:

Specification

The Examiner has objected to the Abstract for not being presented on a separate sheet. The Applicants are submitting herewith an amended Abstract on a separate sheet.

Claim Objections

The Examiner has objected to claims 1 and 15 for containing variables that are not defined in the claims. The Applicants have amended claims 1 and 15 to define the variables in the claims in accordance with the Examiner's suggestions.

Double Patenting

Claims 1-17 and 27 have been provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-24, 32, 33 and 35 of copending Application No. 10/586,226. The Applicants are submitting herewith a Terminal Disclaimer to overcome this rejection.

Claim Rejections – 35 USC § 112

Claims 8, 11 and 15-17 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicants regard as the invention.

In claim 3, the phrase beginning with the word “optionally” has been found to be indefinite. The Applicants have amended claim 3 to delete this phrase. The phrase beginning with the word “optionally” has been added as new claim 31.

In claim 8, the limitation “said non-cyclic monomers” has been found to lack proper antecedent basis. The Applicants have amended claim 8 so that it now depends on claim 6 as the Examiner suggested.

Claims 11 and 15-17 have been rejected for claiming broad ranges as well as narrow ranges within the broad ranges. The Applicants have amended these claims to delete all of the narrow ranges. The narrow ranges have been rewritten as new claims 32-37.

Claim Rejections – 35 USC § 102

Claims 1-10 and 12-17 have been rejected under 35 U.S.C. 102(b) as being anticipated by the article titled “*Macromolecular Chemistry and Physics*” by Penco et al. (“Penco”). Penco discloses multi-block copolymers containing two different biodegradable polyester segments. One of the pre-polymers --poly(ϵ -caprolactone)-- is provided with reactive groups at both ends --poly(ϵ -caprolactone) diol terminated (PVDT)-- which react with the other pre-polymer --poly(lactic-glycolic acid) (PLGA)-- to form alternating multi-block copolymers. *See e.g.*, page 1744, under item 1 of Conclusions.

The amended claims require that the segments of the copolymer are linked by an aliphatic chain-extender and that the segments are randomly distributed in the copolymer. Penco does not teach or suggest block copolymers linked by an aliphatic chain-extender. Penco teaches the preparation of multi-block copolymers containing segments of PLGA coupled with segments of poly(ϵ -caprolactone)s (PEG) by a “chain extension process using

as diols α,ω -bishydroxy-terminated oligomers of caprolactone of different molecular weight.”

However, there is no teaching or suggestion by Penco of a separate PEG chain extender.

Instead, Penco teaches that the segments are functionalized in such a way that the segments can directly react with each other to form a block copolymer.

In the “Results and discussion” section on page 1739, Penco summarizes the synthesis as follows:

The synthetic process for the preparation of PLGA-PCDT segmented copolymers involves the activation of PCDT oligomers by means of phosgene, resulting in the introduction of terminal chloroformate groups. Without isolating, activated PCDTs are then reacted with PLGA oligomers, as represented in Scheme 1.

This synthesis is illustrated at the top of page 1740 of Penco and there is no disclosure that the segments of the copolymer are linked by an aliphatic chain-extender as required by the amended claims. Moreover, Penco does not teach or suggest block polymers wherein the segments are randomly distributed in the copolymer. Accordingly, claims 1-10 and 12-17 are not anticipated by Penco and the Applicants respectfully request that the rejection based on Penco be withdrawn.

Claim Rejections – 35 USC § 103

Claims 1-17 and 27 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Penco in view of U.S. Patent Application Publication No. US 2001/0009662 to Cohn et al. (“Cohn”). Cohn discloses polymeric compositions comprising the reaction product of a diol, diamine or dicarboxylic acid with a chain extender or coupling agent in about a 1:2 mole ratio. The resulting product is reacted with a monofunctional hydroxyl, amine or carboxylic acid containing compound to produce a pentamer. Cohn teaches the synthesis of multi-block

copolymers having a controlled block distribution by using ACA blocks and a monofunctional block AB. This exclusively results in alternating block copolymers having uniform length.

The amended claims require multiblock copolymers wherein the segments of the copolymer are linked by an aliphatic chain-extender and randomly distributed in the copolymer. Cohn teaches the use of aliphatic compounds in the A block (see paragraphs [0092], [0095], [0123], [0124] and [0161] of polymeric compositions but does not teach or suggest the use of aliphatic compounds in the chain extenders. Hence, neither Penco nor Cohn teaches or suggests linking segments in copolymers using an aliphatic chain-extender. Moreover, neither Penco nor Cohn teaches or suggests, either alone or in combination, randomly segmented multi-block copolymers. Instead, the cited references teach alternating multi-block copolymers.

The copolymers of the present invention have the prepolymers distributed randomly and this provides a number of important advantages. For example, the tuning range of the properties of the copolymers (in particular biodegradation, mechanical properties and drug delivery properties) is greatly extended (specification, page 6, lines 18-19) because a different ratio of pre-polymers is possible. This is clearly demonstrated in the Examples of the present application. In the alternating multi-block copolymers of the cited prior art, the ratio of prepolymer components can only be changed when the relative molecular weight of the prepolymers is changed.

Moreover, in contrast to the compositions of alternating copolymers disclosed in the cited references, which can only be determined by adjusting prepolymer lengths, the present

invention is drawn to copolymer compositions of randomly segmented copolymers that are not limited by the prepolymer lengths. The specification discloses at page 12, lines 5-11 that:

The method to obtain a copolymer with a random distribution of a and b (and optionally c) is far more advantageous than when the segments are alternating in the copolymer such as in (ab)_n with the ratio of prepolymers a and b being 1. The composition of the copolymer can then only be determined by adjusting the pre-polymer lengths. In general, the a and b segment lengths in (ab)_n alternating copolymers are smaller than blocks in block-copolymers with structures ABA or AB.

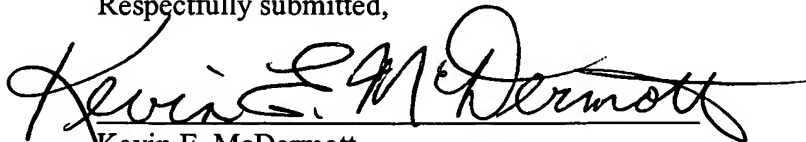
Neither Penco nor Cohn suggests that any advantages can be obtained when the prepolymer segments are randomly distributed in the copolymer, let alone how to arrive at a randomly distributed copolymer, or which specific advantages can be obtained. Hence, the present claims are non-obvious in view of the cited prior art.

Conclusion

Applicants submit that the amendments to the claims and the above arguments clearly distinguish the cited prior art and respectfully request allowance of the claims.

If the Examiner has any questions relating to this amendment, the Examiner is respectfully invited to contact Applicants' attorney at the telephone number provided below.

Respectfully submitted,

A handwritten signature in black ink, reading "Kevin E. McDermott". The signature is fluid and cursive, with the first name "Kevin" and last name "McDermott" clearly legible.

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